

REMARKS

Claims 4, 7-10, 17-22, and 60-84 are pending in this application. Applicants have amended claims 4 and 7-9 without prejudice or disclaimer. Claims 81-84 are new. Support for the amendments and new claims can be found in the application as filed, for example, at page 19, paragraph 0066. No new matter has been added.

Withdrawn Rejections

Applicants thank the Examiner for withdrawing the 35 U.S.C. § 102 and § 103 rejections from the previous Office Action.

Withdrawn Objections

Applicants thank the Examiner for withdrawing the claim objections raised in the previous Office Action.

Double Patenting Rejection

At pages 2-3, the Office maintains its provisional rejection of claim 4 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 7, 9, and 10 of co-pending application no. 11/169,956.

Because neither application has issued as a patent and no conflicting claims have thus been patented, Applicants respectfully defer addressing this rejection (MPEP § 804(I)).

35 U.S.C. §103

The Office at pages 3-6 of the Office Action alleges that claims 4, 7-10, 17-22, and 60-80 are obvious in light of Sorensen et al. (U.S. Pat. No. 5,849,700; “Sorensen”), Singh (U.S. Pat. No. 5,788,959, “Singh”); and DeFelippis et al. (*J. Pharm. Sci.* 87:170-176 (1998); “DeFelippis”).

Applicants respectfully disagree with the Office’s position.

Solely to expedite prosecution, claims 4, 7, 8, and 9 have been amended to recite, *inter alia*, a polyarginine containing crystal of human growth hormone (hGH), wherein the

hGH:polyarginine ratio is 12:1 to 3:1 (w/w). Such a crystal, with the recited ratio (w/w) of hGH to polyarginine, is not obvious in light of the cited references.

Sorensen describes a crystal that contains hGH and histidine or phosphate. It makes no teaching or suggestion of an hGH crystal that contains polyarginine, or of the hGH:polyarginine ratio (w/w) recited in the claims.

Singh describes “a single phase matrix of two oppositely charged polymers (one positive and one negative), which release a drug ...” (Abstract). It is silent on hGH, a polyarginine containing crystal of hGH, and a polyarginine containing crystal of hGH with the specific hGH:polyarginine ratio (w/w) recited in the claims.

Thus, Sorensen and Singh, alone or in combination, do not teach or suggest the claimed subject matter.

DeFelippis does not remedy these defects. DeFelippis describes crystals that contain a particular insulin analogue (or insulin) and protamine. Its disclosure is unrelated to hGH, a polyarginine containing crystal of hGH, or a polyarginine containing crystal of hGH with the specific hGH:polyarginine ratio (w/w).

Further, the only ratios described in DeFillipis are a molar ratio for insulin:protamine of 8:1 (see Abstract) and a molar ratio for the insulin analogue:protamine of 8:1 (see page 173, left column). Its disclosure is unrelated to the claimed subject matter which is drawn to a polyarginine containing crystal of hGH with a specific hGH:polyarginine ratio (w/w).

Even in combination with Sorensen and Singh, the disclosure in DeFelippis fails to render obvious the claimed subject matter, as this combination of references offers no teaching or suggestion whatsoever of a polyarginine containing crystal of hGH, not to mention a polyarginine containing crystal of hGH with the specific hGH:polyarginine ratio (w/w) recited in the claims.

For at least these reasons, Applicants submit that claims 4, 7, 8, and 9 (and their dependencies) are non-obvious in light of the cited references. Withdrawal of this rejection is respectfully requested.

CONCLUSION

For at least the reasons stated above, Applicants respectfully submit that all pending claims are in condition for allowance, which action is expeditiously requested. Applicants do not concede any positions of the Examiner that are not expressly addressed above, nor do Applicants concede that there are not other good reasons for patentability of the presented claims or other claims.

A Request for Continued Examination is being submitted herewith.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. Please charge any deficiency to Deposit Account No. 50/2762.

Respectfully submitted,
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